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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/300,612	04/27/99	LIPPS	B FWLPATU012

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HM12/0718

EXAMINER

BASKAR, P

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED:

07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/300,612

Applicant(s)

LIPPS ET AL

Examiner

Padma Baskar

Group Art Unit

1645

☒ Responsive to communication(s) filed on May 30, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-3, 5, and 7-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5, and 7-16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Response to Amendment

1. The amendment filed on 5/30/00 and 7/3/00 have been entered into the record. Claims 4, 6 and 17 have been canceled and claims 1, 2, 5, 7, 8-11, 13-14 have been amended. Claims 1-3, 5, 7-16 are pending.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Information Disclosure Statement

3. Applicant states that no response is deemed necessary for the previous office action. All references cited by the applicant are not received by the office except the Patents. If the applicant wants the examiner to consider all the references cited, please provide a copy of missing articles.

Rejections Withdrawn

4. Examiner has with drawn 112, second paragraph rejections for claims 1, 2, 9 in view of applicant's amendment to the claims.

Rejections Maintained

5. The rejection of claims 1-3 , 11-13 and 14-15 under 35 U.S.C. 102(b) as being anticipated by Lipps et al 1996 (U.S.Patent No 5,576,297) is maintained. This rejection is maintained for essentially the same reasons as the rejections of claims under this statutory provision, as set forth in the last Office action. Applicants' arguments filed on 5/30/2000, have been fully considered but they are not deemed to be persuasive.

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Lipps et al teaches specific antibodies against LTNF is produced in mice. The antibodies reacted with both natural and synthetic LTNF (column 8 lines 3-10). In the absence of specific teachings the examiner assumes immunized animal produce antibodies (IgG antibodies) in serum, therefore the claims 1-3 and 11-13 are anticipated. Lipps also teaches that his antibodies react with both natural and synthetic toxins, thereby anticipated claims 14-15.

Applicant argues that although Lipps et al produced antibodies to LTNF, the antibodies were not isolated nor their usefulness shown. Claims which are specific as to the purified composition and uses for the composition would thus not be anticipated by Lipps et al. Applicant is arguing the limitations (purified) which are not set forth in the composition claims. At present the composition claims read on Lipps et al as explained above. The claims (1-3, 11-13) are directed to products, not methods, the prior art sets forth the claimed product, regardless of the intended use by the applicants. Lipps et al in column 8, lines 4-11 disclose specific antibodies to LTNF (SEQ.ID.NO 1 in column 9). Therefore, this rejection is maintained.

6. The rejection of claims 1-3, 5 and 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipps et al 1996 (U.S. Patent No. 5,576,297) in view of Harlow and Lane, 1988 (Antibodies: A Laboratory Manual; Chapter 7 and 14) is maintained. This rejection is maintained for essentially the same reasons as the rejections of claims under this statutory provision, as set forth in the last Office action. Applicants' arguments filed on 5/30/2000, have been fully considered but they are not deemed to be persuasive.

Claims are directed to a composition which is an antibody to LTNF_n and LTNFs and its use as a reagent for immunoassays such as ELISA.

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Lipps et al teaches Natural and synthetic lethal toxin neutralizing factors (LTNFn and LTNFs). The prior art teaches fractionation of opossum serum by high pressure liquid chromatography using an anion exchange column. He further teaches amino acid sequencing of the purified LTNF and synthesizing a 15 N terminal peptide which has similar neutralization for toxins (column 3, see summary of the invention). Furthermore, the prior art teaches that LTNFs are immunogenic and mice immunized with it are able to produce specific antibodies, which reacted with both natural and synthetic LTNF (column 8 lines 3-10). Lipps does not specifically teach the monoclonal antibodies, IgG's or an ELISA.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the teachings of Lipps et al to raise monoclonal and polyclonal antibodies to LTNF and use it as a reagent for immunoassays such as ELISA. Methods of making monoclonal and polyclonal antibodies are well known in the art (since the immunogens are known from Lipps et al, 1996). Methods of making monoclonals would necessarily require production of hybridomas and ascites (Harlow and Lane, 1988). An artisan of ordinary skills would have been motivated to raise antibodies to LTNFn and LTNFs because it would have helped in using them for different assays, such as toxin or binding assay as taught by Lipps et al (5,576,297 and 5,744,449). Furthermore, Harlow and Lane also teach that antibodies can be used in assays such as ELISA.

In the absence of unexpected results, the person of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success of obtaining such antibodies and to use them in different assays for detecting toxins etc. The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

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Applicant argues that anti-LTNF not only reacts to LTNF but also other toxins. While LTNF was a universal neutralizing toxin, anti-LTNF is a universal antibody for toxins. Examiner understands and agrees that LTNF is a universal toxin. However, since LTNF is known to be a universal toxin, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use teachings of Lipps et al (antibodies which are reactive to various toxins, column 8, lines 7-11) and Harlow and Lane to perform ELISA assays for anti-LTNF in vitro assay of different biological toxins. Therefore, this rejection is maintained.

New Rejections Based on Amendment

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear to the examiner what is "LTNF-n means?

8. Claims 5, 7-8 are rejected as being vague and indefinite for not having clear method steps for performing ELISA assay. What is the process to bring anti-LTNF and toxin together? Is antibody coated to a plate? What is the immunological reaction caused by toxin and antibody? How is the product identified by ELISA? How are ELISA and Bioassay compared?

9. Claim 9 is rejected as being vague and indefinite for not having clear steps for assessing neutralizing potency of an anti-toxin for a toxin. It is totally confusing how neutralizing index given by an assay for the toxin minus an assay for a mixture of the toxin plus the antitoxin is performed? Is neutralizing index performed with or without anti-LTNF and normal serum?

10. Claims 5 and 14 recite the same limitations. In other words, claim 14 is a duplicate claim of 5.

Status of Claims

11. No claims are allowed.

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Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

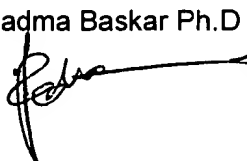
A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

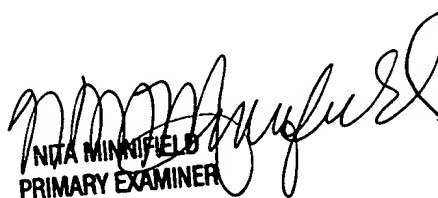
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

 7/12/00


NTA MINNIFIELD
PRIMARY EXAMINER